IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	CRIMINAL ACTION
	:	
v.	:	
	:	
MURTY VEPURI, et al.	:	NO. 21-132

MEMORANDUM

Bartle, J. February 24, 2022

The Government filed a superseding indictment on June 10, 2021, charging defendants KVK-Tech, Inc. ("KVK"), Murty Vepuri, and Ashvin Panchal with one count of conspiracy under 18 U.S.C. § 371 (1) to defraud the United States by impeding, impairing, and defeating the lawful function of the Food and Drug Administration ("FDA"), and (2) to conceal material facts and make false statements in a matter within the jurisdiction of the FDA in violation of 18 U.S.C. § 1001.[1] KVK has also been indicted on a separate count for mail fraud in violation of 18 U.S.C. § 1341. The superseding indictment also charged defendants with conspiring to distribute an unapproved new drug in violation of 21 U.S.C. § 331 and § 355(a). The court has dismissed this latter charge pursuant to Rule 12(b)(3) of the

1. On April 5, 2021, the Government filed an information charging Vepuri on one count for distributing new drugs without FDA approval in violation of 21 U.S.C. §§ 331(d), 333(a)(1). The Government thereafter filed the superseding indictment.

Federal Rules of Criminal Procedure for failure to state an offense.

Now before the court are the motions of Vepuri and Panchal (Docs. # 94, 104) to dismiss the remaining conspiracy count of the superseding indictment as time-barred pursuant to Rule 12(b)(3) of the Federal Rules of Criminal Procedure. The court has entered orders joining each defendant as a movant in the other defendants' motions to dismiss.

I

When considering a motion to dismiss an indictment on the ground that it is time-barred, the court limits its review to the four corners of the indictment and accepts as true its factual allegations. United States v. Huet, 665 F.3d 588, 595-96 (3d Cir. 2012). The defendant may not at this stage challenge the sufficiency of the evidence. United States v. DeLaurentis, 230 F.3d 659, 660 (3d Cir. 2000).

II

The facts are set forth as they are alleged in the superseding indictment. KVK is a generic drug manufacturer based in Newtown, Pennsylvania. Although Vepuri is not named in any of KVK's ownership documents, he is the company's de facto owner and operator. At all relevant times, Panchal was KVK's director of quality assurance.

KVK manufactured and distributed a sedative drug, Hydroxyzine Hydrochloride. In 2007, the Food and Drug Administration ("FDA") approved KVK's Abbreviated New Drug Application ("ANDA") to market this drug. As part of its ANDA, the FDA permitted KVK to produce the drug using an active pharmaceutical ingredient ("API"), hydroxyzine hydrochloride, manufactured only by a Belgian manufacturer, UCB Pharma S.A. ("UCB"). In 2008, KVK filed an application with the FDA to use API produced by another manufacturer, Cosma, S.p.A. in Italy, which the FDA approved.

After an explosion at UCB's facility in 2010, UCB helped KVK purchase the API from a different source, Dr. Reddy's Laboratories ("DRL") in Mexico. Vepuri as KVK's agent authorized this purchase of API. Panchal accepted shipments of the API on KVK's behalf in January, March, and May 2011 and approved their use. He falsely identified the shipments in KVK's internal records as API sourced from Belgium. KVK did not inform the FDA that it was manufacturing the drug using the API from an unapproved source. From April 2011 through December 2013, KVK distributed over 300,000 bottles of the drug using the API from DRL.

Meanwhile in June 2011, the FDA issued a warning letter to DRL stating that it was committing violations of current Good Manufacturing Practices and deeming the API it

produced as "adulterated." Vepuri relayed to Panchal the findings from the FDA's warning letter. The next month, the FDA issued an import alert that authorized the detention of DRL-produced API imported into the United States. The import alert remained in effect until July 2012.

In May 2013 Vepuri authorized another purchase of the API manufactured by DRL. When the shipment arrived at Philadelphia International Airport the next month, the FDA learned of the shipment and ordered it to be detained on the ground that KVK's ANDA did not list DRL as an approved API manufacturer. The FDA refused import of the API into the United States.

On June 28, 2013, the FDA asked KVK to explain its attempt to import the API. Panchal responded via email:

> UCB has changed manufacturing site from [Belgium] to Mexico. CBE-30 Supplement to ANDAs have been submitted to FDA for approval. Upon approval of CBE-30 Supplement, process validation will be performed and one batch will be placed on long-term room temperature stability study.

A month after Panchal sent that email, he filed on KVK's behalf a Change Being Effected in 30 Days Notice ("CBE-30"), which is a method of notifying the FDA of a prospective change to an approved drug that a manufacturer expects to implement within 30 days. See 21 C.F.R. § 314.70(c). In the CBE-30, Panchal asserted that it intended to use the API from DRL and would

await the FDA's approval before distributing the drug with that API. He did not mention that KVK had already begun manufacturing the drug with the unapproved API. The FDA rejected the CBE-30, finding that it proposed a major change for which a more comprehensive application and approval process was needed.

In November and December 2013, the FDA inspected KVK's facilities. Inspectors found photos in KVK's files showing containers of API labeled "Made in Mexico" and stamped with markings in Spanish. During the inspection, Panchal told an FDA inspector that KVK had not received any prior shipments of the API produced by DRL. He stated to the inspectors that he believed UCB had manufactured the detained API, that he did not know that UCB manufactured the API in Mexico, and that he would investigate the matter further. Sometime later, Panchal falsely told inspectors that KVK had disclosed that the API was being manufactured at a new site in Mexico in its annual drug report.

On December 31, 2013, KVK through Vepuri and Panchal informed the FDA in writing that a former employee's "inappropriate regulatory evaluation" caused it to manufacture the drug with the unapproved API. KVK's further stated that it should have investigated "whether or not previous batches had been received."

On June 27, 2014, Vepuri and Panchal met with representatives from the FDA. They continued to make false statements concerning their knowledge of the unapproved API's source at that meeting. The superseding indictment describes the meeting in paragraphs 16 and 17:

> [D]uring a meeting with the FDA, defendants MURTY VEPURI and ASHVIN PANCHAL . . . intentionally misled the agency about [KVK's] use of the unapproved . . . API. Defendants VEPURI and PANCHAL continued to promote the false narrative that a mistake by a former employee had caused the company to inadvertently manufacture and distribute Hydroxyzine containing the . . . API manufactured by DRL in Mexico
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> During the same meeting with the FDA, . . . defendant MURTY VEPURI, with the intent to mislead, identified himself to the FDA as an advisor to [KVK] in order to conceal that he was the de facto owner of the company, and that he directed day-to-day operations and made all key business decisions for [KVK], including decisions related to drug regulatory requirements, drug composition, drug manufacturing quality, purity, and potency, and the purchase of API to manufacture drugs, including the purchase of the API for the manufacture of Hydroxyzine tablets.

The FDA conducted more inspections of KVK's Newtown facilities in November and December 2014. On December 11, Panchal supplied to the FDA a Manufacturing Deviations and Investigations Report. According to paragraph 18 of the superseding indictment,

> [The document] was purportedly a comprehensive report, signed by defendant PANCHAL, detailing [KVK's] investigation and conclusions related to the API manufactured by DRL in Mexico. As defendant PANCHAL knew, the report contained false and misleading information, including that it was "not clear why [UCB] shipped API manufactured in Mexico." As defendant PANCHAL also knew, defendant MURTY VEPURI had authorized the purchase of the API manufactured by DRL in Mexico.

In March 2015, the FDA incorporated Vepuri and Panchal's false statements into a report on its investigation of KVK. Paragraph 19 of the superseding indictment alleges,

> After the FDA released a final Establishment Inspection Report ("EIR") for the second inspection on or about March 2, 2015, defendants [KVK], MURTY VEPURI and ASHVIN PANCHAL, knowing the EIR was substantially false based on information they had provided, failed to notify the FDA of the falsehoods to avoid enforcement action or being required to perform needed corrective actions.

III

The applicable statute of limitations for conspiracy charges under 18 U.S.C. § 371 is five years. See 18 U.S.C. § 3282(a). The limitations period for a charge under § 371 does not begin to run until the completion of the last overt act that furthers the object of the conspiracy. See United States v. Amirnazmi, 645 F.3d 564, 592 (3d Cir. 2011). Although the Government filed the superseding indictment on June 10, 2021, more than five years after the last alleged overt act, it is

undisputed that the limitations period was tolled on several occasions.[2] As a result, the parties agree that for the superseding indictment to be timely as to each defendant, it must assert that Vepuri committed an overt act on or after April 2, 2014 and that Panchal committed an overt act on or after December 8, 2014.

Vepuri and Panchal argue that the superseding indictment does not allege that either committed an overt act on or after those dates based on their description of the alleged conspiracy. They characterize the central criminal purpose of their conspiracy, as alleged, as limited to "distribut[ing] an unapproved new drug." They contend this goal was achieved by December 2013 when KVK delivered to customers the last batch of the drugs made from the unapproved API. Accordingly, they argue that the alleged overt acts that occurred after December 2013 did not further their conspiracy and instead were acts of concealment that under Grunewald v. United States, 353 U.S. 391 (1957), cannot extend the limitations period.

The defendants' argument fails because it requires a rewriting of the superseding indictment in a manner consistent

2. The limitations period was tolled for six months in connection with the Government's efforts to obtain evidence about UCB through the Belgian government pursuant to the Mutual Legal Assistance Treaty. See 18 U.S.C. § 3292(a). The Government is also entitled to tolling through the several statute of limitations waivers it signed with each defendant.

with their version of the facts. The object of defendants' conspiracy as charged in the superseding indictment is broader than defendants' characterization. Beyond distributing the drugs made from the unapproved API, the Government also alleges a conspiracy to defraud the FDA through concealment of material facts, false statements, and misleading representations:

> [Defendants] conspired, combined, and agreed with each other, and with others known and unknown to the Grand Jury:
>
> a. [to] defraud the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public by ensuring that drugs marketed and distributed in the United States were safe and effective for their intended uses; and
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> b. [to] commit an offense against the United States by . . . (2) knowingly and willfully making materially false, fictitious, and fraudulent statements and representations, and falsifying and concealing material facts in a matter within the jurisdiction of the FDA . . . in violation of [18 U.S.C. § 1001].

The Supreme Court ruled in Grunewald that "the crucial question in determining whether the statute of limitations has run is the scope of the conspiratorial agreement, for it is that which determines both the duration of the conspiracy, and whether the act relied on as an overt act may properly be regarded as in furtherance of the conspiracy." 353 U.S. at 397. Concealment activities after the purpose of the conspiracy has

been attained "for the purpose only of covering up after the crime" do not extend the time to file an indictment. See id. at 405. On the other hand, an act of concealment brings the conspiracy within the statute of limitations when "done in furtherance of the main criminal objectives of the conspiracy." See id. For example, in cases involving tax evasion, an indictment may properly allege a "continuing conspiracy to evade taxes that include[s] overt acts of concealment after the taxes were due." United States v. Moses, 148 F.3d 277, 282 (3d Cir. 1998) (Alito, J.).

"The ultimate question of whether acts are in furtherance of the conspiracy or only for purposes of concealment depends on the objectives of the conspiracy, a determination of which is a question of fact for the jury." United States v. Cannistraro, 800 F. Supp. 30, 78 (D.N.J. 1992); see also United States v. Qayyum, 451 F.3d 1214, 1221 (10th Cir. 2006). The court need not decide at this juncture whether Vepuri and Panchal's failure to correct the FDA's Establishment Inspection Report in March 2015 constituted overt acts. The superseding indictment clearly alleges Vepuri committed an overt act on June 27, 2014, when he made intentional false statements about KVK's knowledge of the source of the unapproved API and his role at KVK. It also alleges Panchal committed an overt act on December 11, 2014 when he provided to the FDA a report with

intentional false statements about KVK's knowledge of the source of the unapproved API. Whether the jury will so find is, of course, a matter for another day. For present purposes, the conspiracy charge of the superseding indictment is timely as to Vepuri since the last overt act attributed to him allegedly occurred after April 2, 2014 and is timely as to Panchal as the last overt act attributed to him allegedly occurred after December 8, 2014.[3]

Defendants urge the court to construe the object of the conspiracy more narrowly than the superseding indictment alleges. None of the authorities they cite permits the court to do so. In Grunewald, the Supreme Court's analysis occurred after the trial had taken place. Likewise, United States v. Kang arose from the defendant's motion for judgment of acquittal, and the court acknowledged "the language of the indictment would control for purposes of a motion to dismiss an indictment on statute of limitations grounds." 715 F. Supp. 2d 657, 673 & n.37 (D.S.C. 2010). By contrast, this pending action is in the pretrial stage where the court must accept as true the scope of the conspiracy as delineated in the superseding

3. Panchal maintains that he supplied this report to FDA inspectors on November 20, 2014, and not on December 11, 2014. However, the superseding indictment charges that Panchal supplied this report on December 11, 2014, and the court "must accept as true the factual allegations set forth in the indictment." See Huet, 665 F.3d at 595–96.

indictment. See Cannistraro, 800 F. Supp. at 78; see also Huet, 665 F.3d at 595–96.

Defendants' reliance on United States v. Roshko, 969 F.2d 1 (2d Cir. 1992), is also misplaced. The defendant in Roshko was charged with conspiring to defraud the Government specifically by "seeking changes in the immigration status of [the defendant] based on a sham marriage to a United States citizen." Id. at 2. The only alleged overt acts within the limitations period were the defendant's divorce from his sham bride and his subsequent remarriage. After a jury trial, the defendant was convicted. The Court reversed the district court's judgment of conviction on the ground that the conspiracy charge was time-barred. The Court held that the divorce and remarriage did not extend the limitations period because those acts did not further the defendant's narrowly defined object of obtaining a green card through the sham marriage, which had already been achieved. See id. at 8. Unlike Roshko, this pending action has yet to go to trial. Furthermore, the superseding indictment charges a conspiracy with the broadly defined object of making false statements and misleading representations to the FDA. The alleged acts that defendants characterize as concealment allegedly furthered that broader object.

Based on the four corners of the superseding indictment, the court cannot conclude that Vepuri's and Panchal's acts within the relevant limitations periods "were concealment for purposes of cover-up, as opposed to overt acts in furtherance of the conspiratorial objective." E.g., United States v. Nazzal, Cr. A. No. 11-20759, 2012 WL 4838996, at *6 (E.D. Mich. Oct. 11, 2012). It will be up to the jury to decide the scope of Vepuri's and Panchal's conspiratorial object and whether any overt acts that furthered that object were within the limitations periods.

The motion of defendants Vepuri and Panchal to dismiss the remaining portions of count one of the superseding indictment charging conspiracy under 18 U.S.C. § 371 and § 1001 on the ground that they are time-barred will be denied.